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Amendments to the Specification:

Please amend the paragraph appearing on lines 12-16 of page 2 of the specification as follows:

JP-A-1-268627, JP-A-1-268628 and JP-A-8-27033 disclose pharmaceutical compositions using erythritol, respectively. However, there is no disclosure of solid pharmaceutical composition characterized by fast disintegration in the oral cavity.

Please amend the paragraph appearing on lines 17-21 of page 2 of the specification as follows:

JP-A-9-48726 discloses a buccal formulation consisting of a drug and a substance wetting in a mouldable way on humidifying, and retaining a shape after moulding and drying. As such ~~substance~~ substances, sugars, sugar alcohols and water-soluble polymers are exemplified.

Please amend the paragraph appearing on lines 14-32 of page 3 of the specification as follows:

For many reasons, such as, masking a bitter taste, or providing enteric abilities or release abilities, it is desirable to prepare the solid pharmaceutical preparations as granules (or fine granules). In particular, in case of granules or fine granules in which the active ingredient of the drug is enteric coated to impart enteric dissolution, there is a need for enteric coating to prevent dissolution by stomach acid (i.e., to make the preparation acid-resistance). It is necessary to coat the whole surface of the particle -before the enteric coating- (including a case of the crystal of physiologically active substance only, and a case of the granule produced by granulation), with the enteric coating. Namely, at least some uniform thickness (at least 20 μm or more) of the coating layer is needed. Even a portion of thin and weak coating[[,]] is undesirable because acid-resistance is lowered. Accordingly, before the enteric coating, it is necessary that the particle is as

spherical with smooth surface as possible in form, as uniform as possible in size, and has less cavity.

Please amend the paragraph appearing on lines 29-30 of page 8 of the specification as follows:

[45] fine granules of the above [43], wherein the enteric coating layer further ~~comprise~~ comprises a sustained-release agent;

Please amend the paragraph appearing on lines 15-22 of page 9 of the specification as follows:

"Average particle diameter" means volume based distribution median diameter (median diameter: 50% particle diameter from cumulative distribution), unless otherwise specified. It can be measured by, for example, a laser diffraction particle distribution measurement method. Concretely exemplified is a method using ~~Raser~~ Laser Diffraction Analyzer, type: ~~HEROS~~ HELOS RODOS [trade name; manufactured by Sympatec (Germany)].

Please amend the paragraph appearing on lines 8-13 of page 10 of the specification as follows:

"Practically" as used in "the particle diameter is practically 425 μm or less" and "the particle diameter is practically 400 μm or less" means that the particles may include a small quantity (about 5 weight % or less) of particles whose particle diameter is out of above described range, to include the ~~inevitably~~ inevitable contaminant particles.

Please amend the paragraph appearing on lines 14-30 of page 16 of the specification as follows:

The above "enteric coating layer" which coats the "composition having 10 weight % or more of an acid-labile physiologically active substance" includes, for example, an aqueous enteric polymer agent such as cellulose acetate phthalate (CAP), hydroxypropylmethyl cellulose phthalate (hereinafter, referred to as HP-55), hydroxymethyl cellulose acetate succinate, methacrylate copolymer [e.g., Eudragit L30D-55 etc.(trade name; manufactured by Rohm GmbH (Germany)), ~~KollCoat~~ Kollicoat MAE30DP (trade name; manufactured by BASF (Germany)), Polyquid PA-30 (trade name; manufactured by ~~SanyoKasei~~ Sanyo Kasei (Japan)), etc.], carboxymethyl cellulose, shellac, etc.; a sustained-release agent such as methacrylate copolymer [e.g., Eudragit NE30D (trade name), Eudragit RL30D (trade name), Eudragit RS30D (trade name), etc.]; a water-soluble polymer; plasticizers such as triethyl citrate, polyethylene glycol, acetylated monoglyceride, triacetin, castor oil, etc. and mixtures thereof.

Please amend the paragraph appearing at lines 16-27 of page 18 of the specification as follows:

The "crystalline cellulose" includes refined one having partially α-cellulose depolymerization. Such crystalline cellulose includes one called microcrystalline cellulose. Examples of the "crystalline cellulose" include CEOLUS KG801, ~~avicel~~ Avicel PH101, ~~avicel~~ Avicel PH102, ~~avicel~~ Avicel PH301, ~~avicel~~ Avicel PH302, ~~avicel~~ Avicel RC-591 (crystalline cellulose carmellose sodium), etc. Among these, preferably employed is CEOLUS KG801 which is also called crystalline cellulose of high compressibility. Two or more of the crystalline cellulose can be used as a mixture in a given ratio. Such crystalline cellulose is available on the market, for example, as manufactured by Asahi Chemical Co., Ltd. (Japan).

Please amend the paragraph appearing on lines 16-20 of page 20 of the specification as follows:

The particle diameter of "the low-substituted hydroxypropyl cellulose[[s]] wherein the content of hydroxypropoxyl group is 5.0 to 7.0 weight %" to be used in the

present invention is, for example, about 5 to 60 μm, preferably about 10 to 40 μm, as a average particle diameter.

Please amend the paragraph appearing at lines 21-32 of page 20 as follows:

In the above ranges, in case that low-substituted hydroxypropyl cellulose[[s]] (L-HPC) having a relatively large particle diameter (for example, L-HPC having about 26 to 40 μm of the average particle diameter) is employed, a pharmaceutical preparation superior in disintegrability can be produced. On the other hand, in case that L-HPC having a relatively small particle diameter (for example, L-HPC having about 10 to 25 μm of the average particle diameter) is employed, a pharmaceutical preparation superior in strength of the preparation can be produced. Accordingly, the particle diameter of L-HPC can be suitably selected according to the characteristics of the desired pharmaceutical preparation.

Please amend the paragraph appearing on lines 18-21 of page 22 was follows:

Two or more of these disintegrants can be as a mixture in a given ratio. For example, (i) crospovidone solely, or (ii) crospovidone and another disintegrant(s) ~~is~~ are preferably employed.

Please amend the paragraph appearing at lines 3-8 of page 24 of the specification as follows:

As a pharmaceutical preparation which comprises the "fine granules" of the present invention, there may be employed, for example, a solid preparation such as tablet, granule, fine granule, capsule, effervescent, etc; a liquid preparation such as suspension preparation, etc. Among others, preferred is a tablet, more preferred is an orally disintegrable tablet.

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Please amend the paragraph appearing on lines 27-35 of page 25 and lines 1-3 of page 26 of the specification as follows:

Concrete example of the "rolling granulation method" includes a method using "CF apparatus" manufactured by Freund Industrial Co., Ltd. (Japan) and so forth. Concrete examples of the "rolling fluidized-bed granulation method" include methods using "SPIR-A-FLOW", "~~multi plex~~Multiplex" manufactured by Powrex Corp. (~~U. S. A.~~ Japan), "New-Marumerizer" manufactured by Fuji Paudal Co., Ltd. (Japan), and so forth. The method for spraying the mixture can be suitably selected in accordance with the kind of granulator, and may be, for example, any one of a top spray method, a bottom spray method, a tangential spray method, and so forth. Among others, a tangential spray method is preferred.

Please amend the paragraph appearing at lines 29-34 of page 26 and lines 1-13 of page 27 of the specification as follows:

Examples of the "core" include
(1) a spherical granulated product comprising crystalline cellulose and lactose, (2) a spherical granulated product being about 150 to 250 μm and comprising crystalline cellulose (~~avicel~~ Avicel SP, manufactured by Asahi Chemical Co., Ltd. (Japan)), (3) a stirring granulated product being about 50 to 250 μm and comprising lactose (9 parts) and α starch (1 part), (4) a micro particle being about 250 μm or less classified as a spherical granule comprising micro crystalline cellulose described in JP-A-61-213201, (5) a processed product such as wax formed to a sphere by spraying or melting granulation, (6) a processed product such as gelatin beads comprising oil component, (7) calcium silicate, (8) starch, (9) a porous particle such as chitin, cellulose, chitosan, etc, and (10) a bulk product such as granulated sugar, crystalline lactose or sodium chloride, and processed preparations thereof. Further, these cores may be produced in accordance with a *per se* known grinding method or granulation method, and sifted to prepare the particles having the desired particle diameter.

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Please amend the paragraph appearing at lines 1-11 of page 30 of the specification as follows:

The "fine granule" in the present invention can be produced ~~in accordance with~~ in the same manner as above granulation method, for example, a method which comprises coating the composition with an enteric coating layer, in order to protect the acid-labile physiologically active substance or to impart enteric dissolution. If necessary, the composition coated with an enteric coating layer may be further coated by a water-soluble sugar alcohol, preferably mannitol. In such case, the strength of the orally disintegrable tablet comprising fine granules is improved.

Please amend the paragraph appearing at lines 2-10 of page 31 of the specification as follows:

The "blending procedure" can be carried out by any of the conventional blending techniques such as admixing, kneading, granulating, etc. The above "blending procedure" is carried out, for instance, by using an apparatus such as Vertical Granulator GV10 [manufactured by Powrex Corp. (Japan)], Universal Kneader [manufactured by Hata Iron Works Co., Ltd. (Japan)], ~~fluidized bed~~ fluidized-bed granulator LAB-1 and FD-3S [manufactured by Powrex Corp. (Japan)], V-shape mixer, tumbling mixer, and so forth.

Please amend the paragraph appearing at lines 13-19 of page 33 of the specification as follows:

The "orally disintegrable tablet" of the present invention is advantageously used in (a) cases where administration without water is necessary, (b) cases of administration to [[a]] patients who have difficulty in swallowing tablets, or (c) cases of administration to the aged or to children where there is a fear of blocking the throat if it is in usual tablet form.

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Please amend the paragraph appearing at lines 20-24 of page 33 of the specification as follows:

In case of the above (a), the orally disintegrable tablet is preferably used for antipyretic agents, analgesic agents, anti-inflammatory agents, antianxiety drugs, antitussive-expectorants, ~~anti-motion~~ anti-motion sickness agents, drugs for prevention and treatment for car-sickness, and so forth.

Please amend the paragraph appearing at lines 7-30 of page 34 of the specification as follows:

For instance, when a benzimidazole compound (I) or a salt thereof such as lansoprazole is employed as an acid-labile physiologically active substance, especially a pharmaceutically active ingredient, the "orally disintegrable tablet" of the present invention and the pharmaceutical preparation which comprises the "fine granules" of the present invention is useful for treatment and prevention of digestive ulcer (e.g., gastric ulcer, duodenal ulcer, anastomotic ulcer, Zollinger-Ellison syndrome, etc), gastritis, reflux esophagitis, etc.; eradication of H. pylori; suppression of gastrointestinal bleeding caused by digestive ulcer, acute stress ulcer and hemorrhagic gastritis; suppression of gastrointestinal bleeding caused by invasive stress (e.g., stress caused by cerebrovascular disease, head injury, failure of many organs, burn injury of a wide range, which necessitate a large-scale operation necessitating the following intensive management[[,]] or intensive care); treatment and prevention of ulcer caused by non-steroidal anti-inflammatory agent; treatment and prevention of gastric hyperacidity and ulcer caused by postoperative stress; administration before anesthesia, etc. The dosage of the preparation per an adult (body weight: 60 kg) is about 0.5 to 1,500 mg/day, preferably about 5 to 150 mg/day, as a benzimidazole compound (I) or a salt thereof such as lansoprazole.

Please amend the paragraph appearing on lines 10-12 of page 36 of the specification as follows:

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Determination was carried out with ~~Raser~~ Laser Diffraction Analyzer, type: ~~HEROS~~ HELOS RODOS [trade name, manufactured by Sympatec (Germany)].

Please amend the paragraph appearing at lines 4-16 of page 38 of the specification as follows:

A ~~fluidized-bed~~ fluidized-bed granulator [manufactured by Powrex Corp. (Japan), LAB-1] is charged with 1321.2 g of erythritol [manufactured by Nikken Chemical Co., Ltd. (Japan)], 360.0 g of low-substituted hydroxypropyl cellulose LH-32 [hydroxypropoxyl group contents of 8.8 %, manufactured by Shin-Etsu Chemical Co., Ltd. (Japan)], 18.0 g of citric acid anhydrous, and 1.8 g of aspartame, and granulation is carried out while spraying a solution which is prepared by dissolving 3.6 g of polyethylene glycol (PEG-6000) in 896.4 ml of purified water. The granules are dried to provide granulated powders. To the granulated powders are added 90.0 g of crospovidone and 5.4 g of magnesium stearate, which is admixed in a bag to give mixed powders.

Please amend the paragraph appearing at lines 7-15 of page 39 of the specification as follows:

An alkaline cellulose comprising 24.1 % of NaOH, 1.7 % of Na_2CO_3, 42.9 % of cellulose, and 31.8 % of H_2O was obtained by immersing a wood pulp in 49% aqueous solution of sodium hydroxide and then by pressing it. A reactor was charged with 100 weight parts of the alkaline cellulose. Then, nitrogen gas replacement was carried out. After the replacement, 5 weight parts of propylene oxide was charged in the reactor and reacted with stirring at 40 °C for 1 hour, at 50 °C for 1 hour and at 70 °C for 1 hour to obtain 103 weight parts of a reactant.

Please amend the paragraph appearing at lines 15-19 of page 42 of the specification as follows:

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A ~~fluidized-bed~~ fluidized-bed granulator [manufactured by Powrex Corp. (Japan), LAB-1] was charged with 800 g of mannitol [manufactured by Merck Japan Co., Ltd.], and granulation was carried out while spraying 315 g of purified water. The granules were dried to provide 727.3 g of granulated powders.

Please amend the paragraph appearing at lines 10-11 of page 49 of the specification as follows:

The remaining ratio of the obtained tablet after the acid-resistance test was 97%.

Please amend the paragraph appearing at lines 19-21 of page 67 and lines 1-10 of page 68 of the specification as follows:

A ~~fluidized-bed~~ fluidized-bed granulator [manufactured by Powrex Corp. (Japan), LAB-1] was charged with 1321.2 g of erythritol [manufactured by Nikken Chemical Co., Ltd. (Japan)], 360.0 g of low-substituted hydroxypropyl cellulose LH-32 [hydroxypropoxyl group contents of 8.8 %, manufactured by Shin-Etsu Chemical Co., Ltd. (Japan)], 18.0 g of citric acid anhydrous, and 1.8 g of aspartame, and granulation was carried out while spraying a solution which was prepared by dissolving 3.6 g of polyethylene glycol (PEG-6000) in 896.4 ml of purified water. The granules were dried to provide granulated powders. To the granulated powders were added 90.0 g of crospovidone and 5.4 g of magnesium stearate, which was admixed in a bag to give mixed powders.

Please amend the paragraph appearing on lines 5-14 of page 69 of the specification as follows:

Further, because the fine granule of the present invention is characterized in that it stably retains the acid-labile physiologically active substance, contains the physiologically active substance in high content, ~~be~~ is small and has superior stability, it can be used for producing various compact pharmaceutical preparations such as tablets,

capsules, suspensions and so forth. Such preparations are easy of use at the administration. In addition, the fine granule of the present invention has superior acid-resistance after compression.